



Billing Code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATES: The meeting will be held on Tuesday, March 12, 2013 from 10:30 a.m. until 5:00 p.m. and Wednesday, March 13, 2013 from 8:30 a.m. until 4:30 p.m. Tuesday morning will begin with a two-hour closed administrative session, with the meeting opening to the public at 10:30 a.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue, S.W., Hubert H. Humphrey Building, Room 800, Washington, D.C. 20201.

FOR FUTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive

Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; e-mail address: Julia.Gorey@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On Tuesday, March 12, following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, there will be a presentation from HHS staff describing the history of SACHRP and the process for creating regulatory guidance and regulatory change; a discussion of SACHRP members' priorities for future discussion topics will follow. Subpart A Subcommittee will next discuss their recent work, including considerations for revisions to the expedited review list. Subpart A Subcommittee is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this Subcommittee was established by SACHRP in October 2006.

Following opening remarks on the morning of March 13, a special panel of experts will discuss Improving the Informed Consent Process; this discussion will initiate a new SACHRP spotlight on this topic. The Subcommittee on Harmonization (SOH) will next give a report and discuss their recent work, including an examination of human subject research issues affecting cluster randomized trials, and issues associated with the use of

differing agencies' certificates of confidentiality. SOH was established by SACHRP at its July 2009 meeting and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. SACHRP will conclude Wednesday afternoon with discussion of a revised document on the issue of the use of the internet in human subjects research. Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business March 8, 2013.

Dated: February 15, 2013

Jerry Menikoff,

Director, Office for Human Research Protections

Executive Secretary, Secretary's Advisory Committee on

Human Research Protections

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